

APPLICANT(S): Adrian PAZ
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REMARKS

The present response is intended to be fully responsive to all points of objection and/or rejection which were raised by the Examiner and is believed to place the application in condition for allowance. Favorable reconsideration and allowance of the application is respectfully requested.

Applicants assert that the present invention is new, non-obvious and useful. Prompt consideration and allowance of the claims is respectfully requested.

It is respectfully submitted that no new matter was introduced into the amendments.

Status of Claims

Claims 29-32 and 36-37 are currently pending. Claims 1-28, 33-35 and 38-40 are canceled. Claims 29-32 and 36-37 are currently amended. Claims 41-43 are withdrawn. New claims 44-48 have been added.

Amendment to the Claims

Claim 29 is amended to read:

"A surgery-assisting retraction device (SARD) for use in minimally invasive surgeries within a cavity of the human body, comprising at least one first anchoring means and at least one second anchoring means, said first anchoring means is adapted for attaching said SARD to an internal surface within said cavity and said second anchoring means is adapted for attaching said SARD to an organ within said cavity; wherein said SARD is configured for being entirely inserted into said cavity; further wherein said SARD, when activated, internally retracts said organ with respect to said internal surface such

that no constant external forces applied from the outside of the body are needed to retract said organ"

Support for the phrase "further wherein said SARD, when activated, internally retracts said organ with respect to said internal surface "such that no constant external forces applied from the outside of the body are needed to retract said organ" is found, inter alia, in the 'BACKGROUND OF THE INVENTION' paragraph [003]:

"This invention relates to anchoring devices for retractors and/or for lifting the cavity walls, being attached to the internal surface of a cavity or to various organs within a cavity, during minimally invasive surgery." ; and, in the 'DETAILED DESCRIPTION OF THE INVENTION' paragraph [079]: " The device provides a virtual port, that is an instrument that can be non-invasively, or minimally invasively and removably attached to the undersurface of a patient's cavity, or to various tissues within a cavity, and to which various retracting means or instruments are attached";

and in the 'DETAILED DESCRIPTION OF THE INVENTION' paragraph [091]: *"To the virtual port device may be attached, through a string, a tissue attachment means. This system will cause retraction by pulling toward the anchoring means."*

Support for the phrase " such that no constant external forces applied from the outside of the body are needed to retract said organ" is found, inter alia, in the 'BACKGROUND OF THE INVENTION' paragraph [088]: *"The device can be moved from one position to another and reattached to the undersurface of the abdominal wall, or to various tissues within a cavity, without creating any additional openings in the cavity wall"*

New claims 44-48 are added stating the uses of an introducer.

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Support for claim 44, namely for the phrase "*activated by an introducer*" is found, inter alia, in the 'DETAILED DESCRIPTION OF THE INVENTION' paragraph [121]: "*The device is provided with a protuberant means, preferentially situated opposite to the attachment side to the cavity wall, that permit grasping and handling by the introducer.*"

Support for claim 46, namely for the phrase "*manipulated and relocated*" is found, inter alia, in the 'DETAILED DESCRIPTION OF THE INVENTION' paragraph [122]: "*The same introducer device may serve for changing the position of the device on the inner side of the working cavity wall... the introducer means **will move the virtual port device**...*"

PRIORITY

Certified copies of priority documents GB 0324830.9 and GB 0315479.6 were submitted on March 6, 2009.

CLAIM OBJECTIONS

With respect to the objection of claim 34, said claim has been cancelled.

With respect to the objection of claim 37, the phrase "said controlling means bein" has been amended to read "said controlling means being".

It is respectfully submitted that all the claims are reviewed for informalities and were ensured that all the terms used to identify elements of the claimed invention are consistent.

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CLAIM REJECTIONS

35 U.S.C. §112 Rejections

Claim 33 of the present application is rejected to by the examiner under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement.

With regards to said claim, claim 33 has been cancelled.

Claims 29-34, 36 and 37 of the present application, 10/563,229, are rejected to by the examiner under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

With regards to claim 29, said claim has been amended and the phrase "said surgical instrument holding device" has been deleted from said claim.

With regards to claim 31, said claim has been amended and the phrase "said holding device" has been deleted from said claim.

With regards to claim 33, said claim has been cancelled.

With regards to claim 34, said claim has been cancelled.

With regards to claim 36, said claim has been amended and the phrase "and/or" has been deleted.

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With regards to claim 37, said claim has been amended and the phrases "said surgical instrument holding device", "may be" and "the operator" have been deleted.

35 U.S.C. §101 Rejections

Claim 37 of the present invention is rejected to by the examiner under 35 U.S.C. 101 as being drawn to non statutory subject matter.

Said claim has been amended to read "*The SARD according to claim 29, additionally comprising: controlling means releasably attached to said SARD adapted to (i) introduce said SARD into said cavity; (ii) to extract said SARD from said cavity; and, (iii) to relocate said SARD within said cavity; said controlling means being at least partially operated from outside said body*"

The phrase "by the operator" has been deleted from the claim.

35 U.S.C. §102 Rejections

Claims 29-35 and 37 of the present invention were rejected to by the examiner under 35 U.S.C. 102(e) as being anticipated by Peng, US patent application no. US2003/0009080 (referred to hereinafter as Peng).

The applicant maintains that the concept behind the present application differs from that of Peng.

The present invention provides a surgery-assisting retraction device (SARD) for use in minimally invasive surgeries within a cavity of the human body. The device comprises at least one first anchoring means and at least one second anchoring means.

The first anchoring means attaches the SARD to an internal surface within the cavity and the second anchoring means attaches the SARD to an organ within the cavity.

One of the main emphases lies in the fact that the entire device is introduced into the body cavity. Furthermore, the device, when activated, internally retracts the organ with respect to said internal surface.

It is important to stress out that the device retracts said organ without the need to further apply external forces from the outside of the body to maintain the organ retracted.

Therefore, the device eliminates the need for an anchoring point external to the body in order to retract an organ.

Peng discloses an organ manipulator which includes at least one suction member or adhesive disc mounted to a compliant joint, a flexible locking arm for mounting such suction member or compliant joint.

Peng further discloses a method for retracting and suspending an organ in a retracted position using suction (or adhesive force) so that the organ is free to move normally in at least the vertical direction during both steps.

Peng claims:

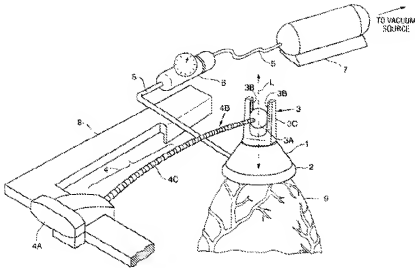
"Claim 1: An organ manipulation apparatus, including: at least one suction member having an inner surface and an outer surface, wherein the suction member is configured to exert sufficient suction force on an organ to move the organ when the suction member is placed against the organ, a pressure differential is established between the inner surface and the outer surface, and the suction member is moved; a support structure; and a compliant joint coupled between the suction member and the support structure, wherein the support structure and the compliant joint are configured to support the suction member, with the organ supported in a retracted position by the suction member, such that the suction member has freedom to move at least along an axis of the suction member relative to the support structure.

*Claim 38: The apparatus of claim 1, wherein the **support structure includes a fixed structure** and an arm adjustably mounted to the fixed structure, the arm has a flexible state and a rigid state, and the arm comprises: a cable; and ball joints threaded along the cable, each of the ball joints having a main portion defining a convex surface and part of a concave socket surface, and an insert portion defining a remaining part of the concave socket surface, wherein the main portion is molded from hard plastic and the insert portion is molded from a material having greater friction than does the hard plastic.*

Peng states the following:

"The mounting structure can be a conventional sternal retractor (of the type used to maintain a sternal incision in an open state for cardiac access), an operating table, or another rigid structure. (paragraph [0023])

The following figure (figure 1 of Peng) illustrates a preferred embodiment of Peng:



Peng states that numerical reference 1 denotes the suction cup, numerical reference 3 denotes the ball sliding joint assembly 3, numerical reference 4 denotes the locking attachment arm 4, numerical references 5-7 denote the suction line, suction flow regulator and vacuum accumulator respectively:

"the inventive apparatus includes the following main elements suction cup 1 (including conforming seal 2 which extends around the periphery of cup 1), ball sliding joint assembly 3, flexible locking attachment arm 4 (which has both a rigid and a flexible state), suction line 5, suction flow regulator 6, and vacuum accumulator 7."

(Paragraph [0070])

"One end of flexible locking attaching arm 4 is attached to sternal retractor 8 (this end can alternately be attached directly to an operating table)..."

(Paragraph [0079])

Figure 1 clearly illustrates that the attaching arm 4 is coupled to both the ball sliding joint 3 and to an external device (i.e., external to the body). As described in the application the external device can be a sternal retractor or alternatively the operating table:

"As shown in FIG. 1, one end of flexible locking attaching arm 4 is coupled to sternal retractor 8 (this end can alternatively be attached directly to an operating table) and the other end of arm 4 is attached to ball sliding joint 3. Ball 3A rides in grooves 3B of element 3C. Cup 1 is mounted rotatably to element 3C (e.g., by a binding screw which couples them together)"

(Paragraph [0079])

Peng does not mention nor claim the possibility of attaching the device internally (no external forces are needed) to an organ and to an internal tissue and hence performing retraction of the organ.

Furthermore, Peng does not mention nor claim the possibility of attaching the attaching arm 4 to an internal tissue whilst the entire device is maintained *within the minimally invasive operated body cavity*. Applications such as Peng are handled and controlled from outside of the body cavity, e.g. held by hand by the surgeon or attached to the operating table, as opposed to the present application in which the device is being fixed inside the body cavity itself. Hence, no external holding forces applied from the outside of the body are needed to retract the organ.

Figure 20 of the present application reproduced below, for example, clearly shows the intent of the present application, namely to provide a support base 51 for a surgical instrument 7, where the support is anchored not by an external member but rather by an internal organ or surface 11.

While both devices, Peng and the present application's device have one end attached to an organ or internal bodily surface, a key difference exists. Namely, the other end of the device, in the case of Peng, attaches to an external anchoring point. In the present application, on the contrary, the other end of the device itself is attached to an **internal tissue** within a body cavity in order to provide retraction of the organ.

A main distinction between the two devices lies in the fact that the device of the present invention provide retraction of the organ without the need to constantly provide external holding forces.

Thus in Peng the external anchor ultimately provides support to hold an internal organ, while in the present application the device provides support (i.e., retraction) internally.

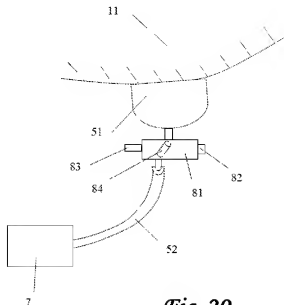


Fig. 20

It is recognized that intended use of a device does not limit its possible anticipation by a structurally identical or similar device with a different intended use. However, the applicant respectfully submits that the device provided in Peng is not only different in intended application but in important structural characteristics.

These differences include:

1. The attachment of one end of the device to an internal organ and the other to an external anchoring point, as opposed to the attachment of *both* end of the device to an internal organ and tissue. This difference necessitates, inter alia, mechanical differences in each device.
2. The design of the Peng device is such that one end will hold an organ within the body cavity and the other will be attached externally to the body (see e.g. Peng

claim 38), while in the current application the entire device resides within the body cavity. This has important ramifications for the use of the device. While the device of Peng can not be used in minimal invasive surgeries, the device of the present application is especially designed to be used in such surgeries.

In minimally invasive surgery, the various tools to be employed must be introduced via a plurality of small-diameter tubes, a mechanical limitation requiring serious engineering effort and dedicated system design to effectively overcome.

Peng does not describe nor claim any use of the device in minimal invasive surgeries. In order to Peng to be used in minimal invasive surgeries several unobvious modifications will have to be made.

Furthermore, Peng can not be used as the device of the present invention.

Another example for the important ramifications for the use of the device (according to the present application) in aiding surgery, for example in those surgeries wherein the body of the patient must be moved during the course of the surgery. In the present application, this movement will be facilitated since the entire device is within the body and moves with it, while in the case of Peng the external anchoring point would have to be moved in tandem with the body of the patient.

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Petition For Two-Month Extension Of Time Under 37 CFR 1.136(a)

The period for responding to the instant Office Action was set to expire on June 10, 2009. Applicant hereby requests that the period for responding to the instant Office Action be extended by two (2) months, so as to expire on August 10, 2009. Accordingly, this response is being timely filed.

The fee for a Petition for a Two-Month Extension of Time is Two Hundred and Forty-Five Dollars (\$245.00) dollars for a small entity. The United States Patent and Trademark Office is hereby authorized to charge Deposit Account 501380 in the amount of \$245.00 and any additional fee which is necessary in connection with the filing of this amendment and petition.

Favorable action on this amendment is courteously solicited.

Respectfully submitted



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